UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

DATE: 13-SEP-1999

SUBJECT: PP# 1F04030. Myclobutanil (Nova®/Rally®) Fungicide in or on Tomatoes and Tomato Processed Fractions. **Amendment of Memos Dated 10/26/92 and 7/13/94.** MRID#s 446798-03 and -04. Barcode D251632. Chemical 128857. Case 282828. Submission S551677.

FROM: Jennifer E. Rowell, Chemist
Registration Action Branch 1
Health Effects Division (7509C)

THROUGH: George F. Kramer, Ph.D., Chemist
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Registration Action Branch 1
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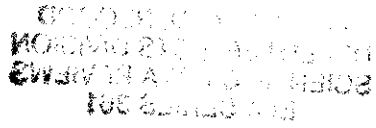
TO: Mary Waller, PM Team 21
Registration Division (7505C)

Rohm and Haas Company requests the establishment of permanent tolerances for the combined residues of myclobutanil, (α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile) and its metabolite, α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) in or on the following tomato commodities:

tomatoes	0.3 ppm
tomatoes, pomace, wet	3.0 ppm
tomatoes, pomace, dry	5.0 ppm
tomatoes, juice	0.3 ppm
tomatoes, puree	0.6 ppm
tomatoes, paste	1.2 ppm
tomatoes, paste juice	0.6 ppm
tomatoes, catsup	0.6 ppm



REGULATORY BACKGROUND

The following terms, as defined below, are used interchangeably throughout this review: (i) **myclobutanil**: RH-3866; α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile; and (ii) **alcohol metabolite**: RH-9090; α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile).

Permanent tolerances are currently established for the combined residues of myclobutanil and its RH-9090 metabolite (free and bound) in/on a variety of agricultural commodities at levels ranging from 0.02 to 25.0 ppm and in meat, milk, poultry, and eggs at levels ranging from 0.02 to 1.0 ppm [40 CFR §180.443(a)].

Time-limited tolerances in conjunction with Section 18 registrations have been established for: artichokes (1.0 ppm; expires 7/31/00); asparagus (0.02 ppm, expires 7/31/00); caneberries (1.0 ppm; expires 12/31/99); cucurbit vegetable group (0.3 ppm, expires 5/30/00); hops, dried (5.0 ppm; expires 12/31/99); peppermint (2.5 ppm, expires 1/31/00); peppers, bell and non-bell (1.0 ppm, expires 7/31/00); spearmint (2.5 ppm, expires 1/31/00); strawberries (0.5 ppm; expires 3/31/00); tomatoes (0.3 ppm, expires 7/28/98); tomato paste (1.2 ppm, expires 7/28/98); and tomato puree (0.6 ppm, expires 7/28/98) [40 CFR §180.443(b)].

The current amendment addresses deficiencies identified in HED's previous reviews (Memos, J. Stokes, 10/22/92 and 7/13/94).

Executive Summary of Chemistry Deficiencies

- Revised Section B.
- Revised label.
- Additional tomato crop field trial data.

RECOMMENDATIONS

The residue chemistry database supports the establishment of following proposed tolerances for the combined residues of the myclobutanil and its metabolite RH-9090 (free and bound):

tomatoes	0.3 ppm
tomatoes, puree	0.6 ppm
tomatoes, paste	1.2 ppm

However, the registration on tomatoes should be conditional until the deficiencies as detailed in Conclusions 1, 2a-c, and 3 are resolved. A human-health risk assessment will be prepared as a separate document.

CONCLUSIONS

OPPTS GLN 860.1200: Proposed Uses

1. The label does not specify a maximum seasonal application rate for myclobutanil on tomatoes. The petitioner should submit a revised Section F to include a maximum seasonal application rate of 0.25 lb. ai/A.

OPPTS GLN 860.1500: Crop Field Trials

2a. A total of 15 field trials have been conducted in the following states: CA(5), FL(3), IN (1), MI (1), NJ(2), OH(2), and SC (1). However, only 6 of these trials were conducted at application rates at or above the maximum proposed single application rate of 0.1 lb. a.i./A. HED is willing to accept the trial in which the total application rate was 0.34 lb. a.i./A (0.99 lb. a.i./A/app.). According to the current guidance (Table 1 of OPPTS 860.1500), for the establishment of a tolerance on tomatoes, a minimum of 16 trials should be conducted and the following geographic distribution is recommended: Region 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (1 trial), 10 (11 trials). The acceptable trials were performed in the following regions: Region 2 (1 trial), 3 (3 trials), 5 (1 trial), and 10 (2 trials). Therefore, 9 additional tomato trials should be conducted using the maximum proposed application rate of 0.1 lb. a.i./A and 0-day PHI. HED recommends that the nine trials be conducted in Regions 1 (1 trial) and 10 (8 trials). The database supports a conditional registration until the additional data are submitted.

2b. Although no field residue data were submitted using applications at the proposed maximum individual application rate of 0.1 lb a.i./A, the residue levels at the 0.125 lb a.i./A (1.25x) application rate are less than the proposed tolerance of 0.3 ppm. The available data are adequate and support a tolerance of 0.3 ppm for residues of myclobutanil and its alcohol metabolite RH-3866 in/on tomatoes.

2c. A final decision on the appropriate tolerance level will be withheld pending submission of the requisite residue data.

OPPTS GLN: 860.1520: Processed Food/Feed

3. As the following processed tomato commodities are not included in Table 1 of OPPTS 860.1500, tolerances are not required: tomatoes, pomace, wet; tomatoes, pomace, dry; tomatoes, juice; tomatoes, paste juice; and tomatoes, catsup. The petitioner should submit a revised Section F with these processed tomato commodities deleted.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1b (from Memo, J. Stokes 10/26/92)

1b. The petitioner must adequately define the isomeric purity (i.e., racemic mixture of enriched enantiomer) of the technical grade active ingredient that is used in myclobutanil formulations. The petitioner should also state which enantiomer is fungicidally active.

Petitioner's Response: Myclobutanil is a racemic mixture and both isomers are active (Correspondence, S. Longacre 10/19/98; MRID# 446798-00).

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 2 (from Memo, J. Stokes 10/26/92)

2. CBTS does not distinguish between "fresh marked" and "processed" tomatoes based upon the knowledge that "fresh market" tomatoes can be processed if the conditions arise. Therefore the minimum PHI of 0 days will be used to assess the field residue data for the tolerance request.

Petitioner's Response: Revised Label

HED's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 4 (from Memo, J. Stokes 10/26/92)

4. Until the additional tomato metabolism and the 28-day feeding study are submitted and reviewed, we will reserve our comments on the nature of the residues in livestock for the proposed use on tomatoes.

Petitioner's Response: None

HED's Conclusion: Metabolism data can be translated from the previous fruit and wheat studies for the tolerance request. The residues are now adequately understood for the proposed use in tomatoes. Therefore, a tomato metabolism study will no longer be required for the proposed use in/on tomatoes (Memo, J. Stokes 7/13/94; Barcode D203587). According to HED Residue Chemistry Guidelines (OPPTS 860.1000; August, 1996) tomato and processed tomato commodities are no longer considered to be animal feed items. Therefore, the 28-day feeding study are no longer required to support a permanent tolerance for residues of myclobutanil in/on tomatoes. This deficiency is now resolved.

Deficiency - Conclusion 6 (from Memo, J. Stokes 10/26/92)

6. A storage stability study must be submitted reflecting the same storage conditions as the tomato samples (both r.a.c. and processed commodities) analyzed in this petition. Also, if additional metabolites must be regulated as determined from the tomato metabolism study, then storage stability data will be needed for these metabolites.

Deficiency (from Memo, J. Stokes 7/13/94)

Although storage stability will not by needed for additional metabolites, storage stability data for tomatoes and tomato processed commodities are still needed for parnet [parent] and its metabolite RH-9090.
Deficiency #6 (Memo of 10/26/92, J. Stokes) is still outstanding.

Petitioner's Response: Submission of the following storage stability study:

Storage Stability Study: RH-3866 & RH-9090 in Tomatoes. MRID# 446798-04.

In this study, 10g of frozen homogenized tomato samples were weighed in 25 ml polypropylene round bottles. The samples were spiked with a solution of RH-3866 and RH-9090, each at a concentration of 1.0 ppm, and stored at approximately -10°C until analyzed. Two samples of the processed tomato samples, a control sample, and two fresh fortified samples were analyzed concurrently at the following time intervals: 0, 3, 6, 12, 18, 24, 30, and 36 months. The samples were analyzed with Rohm and Haas Analytical Method TR 34S-88-10 (MRID# 40803302), with minor modifications. The quantification of RH-3866 and RH-9090 residues was done via gas chromatography using a RTX-35 30 m column and a Capillary Thermionic Specific Detector. For both analytes, the limit of quantitation (LOQ) is 0.01 ppm. Tables 1 and 2 summarize the storage stability of RH-3866 and RH-9090, respectively.

Table 1. Storage Stability of RH-3866 in Tomato.

Storage Period (months)	Fresh Fortified Recovery (%)		Aged Sample Recovery (%)		Average (%) Recovery		Corrected % Recovery
	#1	#2	#1	#2	Fresh	Aged	
0	91.2	94.4	90.6	85.1	92.8	87.9	94.7
3	88.8	76.3	84.7	73.8	82.6	79.3	96.0
6	80.1	88.9	83.5	72.1	84.5	77.8	92.1
12	68.1	72.6	78.6	78.1	70.4	78.4	111
18	97.1	101	104	109	99.1	107	108
24	88.5	94.1	103	98.9	91.3	101	111
30	115	103	117	106	109	112	103
36	92.5	95.8	99.0	101	94.2	100	106

NOTES:
1. corrected % recovery = 100 X (average recovery in aged samples / average recovery in fresh samples)
2. Analytical Method TR 34S-88-10, Method LOQ=0.01 ppm, LOD=0.003 ppm
3. When recovery is >100%, decimals are ignored in reporting data
4. Control sample at 18 month interval contained 0.0221 ppm RH-3866

Table 2. Storage Stability of RH-9090 in Tomato.

Storage Period (months)	Fresh Fortified Recovery (%)		Aged Sample Recovery (%)		Average (%) Recovery		Corrected % Recovery
	#1	#2	#1	#2	Fresh	Aged	
0	86.3	88.0	92.8	100	87.2	96.4	111
3	62.3	68.1	61.1	65.0	65.2	63.1	96.8
6	88.3	80.9	73.2	68.5	84.6	70.9	83.9
12	78.8	86.3	86.3	84.4	82.6	85.4	103

Storage Period (months)	Fresh Fortified Recovery (%)		Aged Sample Recovery (%)		Average (%) Recovery		Corrected % Recovery
	#1	#2	#1	#2	Fresh	Aged	
18	95.4	102	79.5	90.3	98.7	84.9	86.0
24	73.0	71.7	81.6	81.2	72.4	81.4	112
30	79.4	83.2	102	93.4	81.3	97.7	120
36	91.4	101	104	114	96.2	109	113

NOTES:
1. corrected % recovery = 100 X (average recovery in aged samples / average recovery in fresh samples)
2. Analytical Method TR 34S-88-10. Method LOQ=0.01 ppm, LOD=0.003 ppm
3. When recovery is >100%, decimals are ignored in reporting data
4. Control sample at 3 and 6 month intervals contained 0.0467 and 0.0433 ppm RH-9090, respectively

HED's Conclusion: The submitted storage stability data adequately demonstrate that myclobutanil and its alcohol metabolite are stable in tomatoes for at least 36 months under frozen conditions. The average corrected recovery was 103% for both RH-3866 and RH-9090. The maximum amount of time that the samples from the submitted crop field study (MRID# 446798-03) remained in frozen storage prior to analysis was 394 days. HED concludes that myclobutanil and its alcohol metabolite are stable for this time period. The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 7 (from Memo, J. Stokes 10/26/92)

7. No field residue data were submitted using applications at the maximum individual application rate of 0.1 lb a.i./A. Additional residue data must reflect the petitioner's proposed use pattern at the maximum rate and the minimum PHI for all tomatoes to include a cherry of salad size variety. Supporting storage stability data should by included. Also, if additional metabolites must be regulated as determined from the tomato metabolism study, then field residue data will be needed for these metabolites.

Deficiency (from Memo, J. Stokes 7/13/94)

Likewise, residue data will not be needed for additional metabolites, but additional residue data are still needed. **Deficiencies #7 and # 8 are (Memo of 10/26/92, J. Stokes) are still outstanding.**

Petitioner's Response: Submission of the following magnitude of residue study:

Myclobutanil Field Residue Trials on Salad-Type Tomatoes: RAR 93-0085, 93-0127, 93-0154, 93-0156, 94-0001, 94-0042. MRID# 446798-03.

Residue data were submitted depicting the magnitude of residue of myclobutanil in/on salad-type tomatoes. Six field trials were conducted in 1993-94 in the following states: CA(2), FL(2), NJ(1), and OH(1). Four (and in one case 5) applications of Nova® 40W were applied at intervals of 10-16 days, beginning at blossom initiation. Each application was made by either ground (airblast sprayer with a hollowcone multinozzle) or air (flat fan sprayer or hollowcone nozzle) at two rates of 0.063 lb a.i./A (0.63x) and 0.125 lb a.i./A (1.25x), resulting in total application rates of 0.25 lb a.i./A and 0.63 lb a.i./A, respectively. The samples were harvested on the final day of

application (0-day PHI) after sufficient time was allowed for the application to air dry. Samples were also collected at 5, 10, and 15 days following the last treatment.

Samples were either immediately frozen or shipped fresh via overnight to Rohm and Haas Research Laboratories, where they were stored frozen until analysis. All sample were processed and then analyzed for RH-3866 and RH-9090 using the following reference method: TR 34S-88-10 Systhane Total Residue Analytical Method for Parent and Metabolites (MRID# 40803302). Sample fortification levels ranged from approximately 0.01 ppm to 5 ppm. The LOQ is 0.01 ppm. At the 0.063 lb a.i./A application rate, total residues (RH-3866 and RH-9090) ranged from 0.0099 to 0.0576 ppm, with an average of 0.0294 ppm. At the 0.125 lb a.i./A application rate, total residues ranged from 0.0243 to 0.118 ppm, with an average of 0.0698 ppm. Table 3 lists a summary of the residues of both RH3866 and RH-9090.

Table 3. Residue Data Summary: Treatment to Harvest Interval = 0-Day

Site	Variety	Application Rate (lb. ai/A)		SAI [1] (days)	Uncorrected Residues (ppm)		
		Per App.	Total		RH-3866	RH-9090	Total
Fresno, CA	Dwarf Cherry	0.063	0.25	394	0.0099	0	0.0099
		0125	0.5		0.0243	0	0.0243
Carneys Point, NJ	Sweet 100	0.063	0.25	292	0.0483	0.0098	0.0576
		0125	0.5		0.0981	0.0207	0.118
San Luis Rey, CA	BHN 101	0.063	0.25	265	0.0303	0.0064	0.0364
		0125	0.5		0.0825	0.0222	0.104
Fremont, OH	Sweet 100	0.063	0.315	332	0.0182	0	0.0182
		0125	0.63		0.0702	0.0172	0.0865
Boynton Beach, FL	Cherry Grande	0.063	0.25	201	0.0240	0.0059	0.0296
		0125	0.5		0.0299	0.0107	0.0400
Ft. Pierce, FL	Cherry Grande	0.063	0.25	122	0.0245	0	0.0245
		0125	0.5		0.0426	0.0046	0.0469

1. SAI = Sampling to Analysis Interval.

Control and fresh fortification samples were extracted and analyzed concurrently with the field samples. The average fresh fortified recoveries were 79.6% and 68.4% for RH-3866 and RH-9090, respectively. The results are listed in Table 4.

Table 4. Percent Recovery of RH-3866 and RH-9090 on Fresh Fortified Tomatoes.

Run No.	RH-3866			RH-9090		
	Fortified (ppm)	Found (ppm)	Recovery (%)	Fortified (ppm)	Found (ppm)	Recovery (%)
1	2.182	1.63	74.7	2.064	1.16	56.0
	0.0109	0.00849	77.8	0.0129	0.00822	63.7
2	5.455	4.13	75.6	5.16	3.80	73.5
	0.05455	0.0462	84.5	0.0516	0.0351	68.0
3	0.05455	0.0354	64.9	0.0516	0.0366	70.9
	0.05455	0.0537	98.4	0.0516	0.0363	70.3
	2.183	1.78	81.4	2.064	1.57	76.2
Recovery mean ± sd			79.64± 10.344			68.37 ± 6.724

In addition to the 0-day treatment-to-sample-interval (TSI) samples, the samples at TSI-5,10 and 15 were analyzed in order to obtain residue decline data. No evidence of significant decline in magnitude of the total residue was noted over a 15-day period following treatment.

HED's Conclusion: Data depicting the combined residues of myclobutanil and its alcohol metabolite were previously submitted (MRID# 42019201, 42019202, and 42310701) and reviewed by HED (Memo, J. Stokes; Barcode D169217). Nine trials were performed in the following states: CA (3), FL (1), IN (1), MI (1), NJ (1), OH (1), and SC (1). Four or five applications of myclobutanil were made at 0.063 lb. ai/A (0.63x), for total application rates of 0.24 - 0.30 lb. ai/A. In the one trial performed in FL myclobutanil was applied four times for a total application rate of 0.34 lb ai/A. The maximum total residues (parent the metabolite) on tomatoes harvested at 0-day PHIs were seen at this trial was 0.25 ppm.

A total of 15 field trials have been conducted in the following states: CA(5), FL(3), IN (1), MI (1), NJ(2), OH(2), and SC (1). However, only 6 of these trials were conducted at application rates at or above the maximum proposed single application rate of 0.1 lb. a.i./A. HED is willing to accept the trial in which the total application rate was 0.34 lb. a.i./A (0.085 lb. a.i./A/app.). According to the current guidance (Table 1 of OPPTS 860.1500), for the establishment of a tolerance on tomatoes, a minimum of 16 trials should be conducted and the following geographic distribution is recommended: Region 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (1 trial), 10 (11 trials). The acceptable trials were performed in the following regions: Region 2 (1 trial), 3 (3 trials), 5 (1 trial), and 10 (2 trials). Therefore, 9 additional tomato trials should be conducted using the maximum proposed single application rate of 0.1 lb. a.i./A and 0-day PHI. HED recommends that the nine trials be conducted in Regions 1 (1 trial) and 10 (8 trials). **The database supports a conditional registration until the additional data are submitted.**

Although no field residue data were submitted using applications at the proposed maximum individual application rate of 0.1 lb a.i./A, the residue levels at the 0.125 lb a.i./A (1.25x) application rate are less than the proposed tolerance of 0.3 ppm. **Therefore, the available data are adequate and support a tolerance of 0.3 ppm for residues of myclobutanil and its**

alcohol metabolite RH-3866 in/on tomatoes. A final decision on the appropriate tolerance level will be withheld pending submission of the requisite residue data.

The label does not specify a maximum seasonal application rate for myclobutanil on tomatoes. **The petitioner should submit a revised Section F to include a maximum seasonal application rate of 0.25 lb. ai/A.**

Deficiency - Conclusion 8 (from Memo, J. Stokes 10/26/92)

8. The submitted processing study shows concentrations of myclobutanil residues in catsup, puree, paste, paste juice, and pomace when the myclobutanil formulation was applied at a rate of 0.25 lb a.i./A/yr. There appears to be no concentration in juice. We will consider the catsup, puree, and paste juice together as tomato processed products (excluding paste) and have calculated average concentration values of 1.6x for the residue of parent RH-3866 and its metabolite RH-9090 on these products. Therefore, food additive tolerances are needed for tomato processed products (excluding paste) at 0.6 ppm, for paste at 1.2 ppm, and for pomace (wet and dried) at 5 ppm. Also if additional metabolites must be regulated as determined from the requested tomato metabolism study, then processing data will be needed for these metabolites.

   The petitioner must submit a revised Section F. The petitioner should also determine the quantitation limits for myclobutanil and metabolite RH-9090 in whole tomatoes and tomato processing commodities.

Petitioner's Response: A revised Section F with the following proposed tolerances:

tomatoes, pomace, wet	3.0 ppm
tomatoes, pomace, dry	5.0 ppm
tomatoes, juice	0.3 ppm
tomatoes, puree	0.6 ppm
tomatoes, paste	1.2 ppm
tomatoes, paste juice	0.6 ppm
tomatoes, catsup	0.6 ppm

In addition, the petitioner provided the following information: The LOQ used in this study is 0.01 ppm. Although no fortifications were done in the study at the method LOQ of 0.01 ppm, the fortification levels in the study covered the range of residue values observed (Correspondence, S. Longacre 10/19/98).

HED's Conclusion: The tolerances for the processed tomato commodities were previously calculated by multiplying the corresponding concentration factors by the tolerance for tomatoes (0.3 ppm). Current HED guidelines require that in order to calculate the appropriate tolerance for processed commodities, the concentration factors should be multiplied by the highest average field trial (HAFT) value from the crop field trial studies. Therefore, the tolerances for tomato puree and paste have been recalculated to reflect current HED guidelines.

Table 5. Concentrations Factors of Myclobutanil in Tomato Processed Fractions[1]

Commodity	App. Rate lb. a.i./A	Concentration Factors	Average Concentration Factor
Tomatoes, puree	0.25	1.90	1.54
	0.50	1.17	
Tomatoes, paste	0.25	3.30	3.60
	0.50	3.90	

1. (Memo, J. Stokes, 10/16/92, D169217)

The HAFT value for tomatoes in the submitted crop field trials was 0.25 ppm (MRID#s 42019201, 42019202, and 42310701). Utilizing the above concentration factors, the appropriate tolerance levels for tomato puree and paste are 0.50 ppm (1.54 x 0.25 ppm = 0.39 ppm, rounded up to 0.50) and 1.0 ppm (3.60 x 0.25 ppm = 0.90 ppm, rounded up to 1.0).

As the following processed tomato commodities are not included in Table 1 of OPPTS 860.1500, tolerances are not required: tomatoes, pomace, wet; tomatoes, pomace, dry; tomatoes, juice; tomatoes, paste juice; and tomatoes, catsup. The petitioner should submit a revised Section F with these processed tomato commodities deleted. The revised Section F should contain the following:

tomatoes, puree	0.5 ppm
tomatoes, paste	1.0 ppm

Deficiency - Conclusion 9 (from Memo, J. Stokes 10/26/92)

9. The petitioner must submit a conventional 28-day feeding study for lactating dairy cattle at 1x, 3x, and 10x levels based upon the maximum regulated residues expected in all potential feedstuffs. The established tolerances for myclobutanil residues in meat, milk, poultry, and eggs to cover secondary residues from the proposed use on tomatoes requested in the petition as well as the currently established uses will be reevaluated after the additional 28-day lactating cattle feeding study is submitted and reviewed.

Petitioner's Response: Although tomatoes were considered livestock feed materials back in the early 1990's during the initial Agency reviews, the recently revised Residue Chemistry Guidelines (OPPTS 860.1000; August, 1996) do not identify tomatoes or tomato processed fractions as a livestock feed component. Therefore, the myclobutanil 28-day feeding study is not longer required to support the myclobutanil petition (Correspondence, S. Longacre 4/9/99).

HED's Conclusion: Tomatoes and processed tomato commodities are no longer considered to be animal feed items (Table 1 of OPPTS 860.1000). Therefore, the 28-day feeding study is no longer required to support a Section 3 registration of the use of myclobutanil on tomatoes. This deficiency has now been resolved.

cc: PP#1F04030, J. Rowell (RAB1)
RDI: M. Morrow (9/13/99), RAB1 Chemists (9/2/99), G. Kramer (9/2/99).
J. Rowell:806W:CM#2:(703)305-5564:7509C:RAB1

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Date of memo 10/22/92

MEMORANDUM

Subject: PP#1F4030/H5616. Myclobutanil in/on Tomatoes and Tomato Processed Fractions. Evaluation of Analytical Method and Residue Data. MRID #'s 420192-01, 420192-02, 423107-00, and 423107-01. CBTS#'s 8711, 8712, 10106, and 10107. DP Barcodes 169217, 169222, 179690, and 179699.

FROM: Jerry B. Stokes, Chemist
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

THRU: Debra Edwards, Acting Chief
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

TO: Susan Lewis, PM-21
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

Rohm and Haas Company proposes a 0.3 ppm tolerance be established on the r.a.c. tomato and food additive tolerances for tomato processed fractions including wet pomace (3.0 ppm), dry pomace (5.0 ppm), juice (3.0 ppm), puree (0.4 ppm), paste (2.0 ppm), paste juice (0.8 ppm), and catsup (0.7 ppm) for the combined residues of the fungicide myclobutanil [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, RH-3866] and both the free and bound forms of its metabolite [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, RH-9090].

Tolerances have been established (40 CFR 180.443; 185.4350; 186.4350) for myclobutanil. Tolerances for the combined residues of myclobutanil and its metabolite RH-9090 (free and bound) are 0.5 ppm in/on apples (5 ppm in/on wet and dry pomace), 1.0 ppm in/on grapes (10 ppm in/on wet and dry pomace), and 10 ppm in/on raisins

(25 ppm in/on raisin waste). A crop group tolerance has been established in/on pome fruit at 0.5 ppm. The tolerance for milk at 0.05 ppm is established for the combined residues of myclobutanil, its metabolite RH-9090 (free and bound), and metabolite RH-0294 [α-(4-chlorophenyl)-α-(3,4-dihydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile].

Tolerances for the combined residues of myclobutanil and its RH-9090 (free) metabolite are 0.05 ppm for meat, fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep; 0.3 ppm for liver of cattle, goats, hogs, horses, and sheep; 0.02 ppm for meat, fat, and meat by-products of poultry; and 0.02 ppm for eggs.

A temporary tolerance of 2.0 ppm is established on stone fruit (except prune type plums). Temporary tolerances are pending for tomatoes and tomato processed products in PP#2G4059/2H5622 (See memo of 9/30/92, J. Stokes) to cover residues that will be incurred under a proposed EUP which is scheduled for the eastern and western sectors of the US (11 states, 66 trials of 5 acres each over a 2-year period).

Comments/Conclusions

1a. The manufacturing process has been adequately discussed in previous tolerance requests. CBTS concludes that impurities are not likely to be a residue problem.

1b. The petitioner must adequately define the isomeric purity (i.e., racemic mixture or enriched enantiomer) of the technical grade active ingredient that is used in myclobutanil formulations. The petitioner should also state which enantiomer is fungicidally active.

2. CBTS does not distinguish between "fresh market" and "processed" tomatoes based upon the knowledge that "fresh market" tomatoes can be processed if the conditions arise. Therefore the minimum PHI of 0 days will be used to assess the field residue data for this tolerance request.

3. Metabolism data cannot be translated from the previous fruit and wheat studies for this tolerance request. The residues are not adequately understood for the proposed use in tomatoes. Therefore, a tomato metabolism study should be submitted using myclobutanil containing the 14C-radiolabel in the phenyl and triazole rings and at an adequate application rate to identify metabolites.

4. Until the additional tomato metabolism and the 28-day feeding study are submitted and reviewed, we will reserve our comments on the nature of the residues in livestock for the proposed use on tomatoes.

5. The analytical method for determining the residues of parent (RH-3866) and metabolite RH-9090 (free and bound) in tomatoes is adequate. Previously validated methods, including those for milk and meat, for the determination of RH-3866 and RH-9090 have been submitted to PAM II for publication.

   However, we will reserve our final comments on the adequacy of the analytical methodology for enforcement purposes for myclobutanil residues in/on tomatoes until the tomato plant metabolism study has been submitted and reviewed.

6. A storage stability study must be submitted reflecting the same storage conditions as the tomato samples (both r.a.c. and processed commodities) analyzed in this petition. Also, if additional metabolites must be regulated as determined from the tomato metabolism study, then storage stability data will be needed for these metabolites.

7. No field residue data were submitted using applications at the maximum individual application rate of 0.1 lb a.i./A. Additional residue data must reflect the petitioner's proposed use pattern at the maximum rate and the minimum PHI for all tomatoes to include a cherry or salad size variety. Supporting storage stability data should be included. Also, if additional metabolites must be regulated as determined from the tomato metabolism study, then field residue data will be needed for these metabolites.

8. The submitted processing study shows concentrations of myclobutanil residues in catsup, puree, paste, paste juice, and pomace when the myclobutanil formulation was applied at a rate of 0.25 lb a.i./A/yr. There appears to be no concentration in juice. We will consider the catsup, puree, and paste juice together as tomato processed products (excluding paste) and have calculated average concentration values of 1.6X for the residues of parent RH-3866 and its metabolite RH-9090 on these products. Therefore, food additive tolerances are needed for tomato processed products (excluding paste) at 0.6 ppm, for paste at 1.2 ppm, and for pomace (wet and dried) at 5 ppm. Also if additional metabolites must be regulated as determined from the requested tomato metabolism study, then processing data will be needed for these metabolites.

   The petitioner must submit a revised Section F. The petitioner should also determine the quantitation limits for myclobutanil and metabolite RH-9090 in whole tomatoes and tomato processed commodities.

9. The petitioner must submit a conventional 28-day feeding study for lactating dairy cattle at 1X, 3X, and 10X levels based upon the maximum regulated residues expected in all potential

feedstuffs. The established tolerances for myclobutanil residues in meat, milk, poultry, and eggs to cover secondary residues from the proposed use on tomatoes requested in this petition as well as the currently established uses will be reevaluated after the additional 28-day lactating cattle feeding study is submitted and reviewed.

10. There are no Codex, Canadian, or Mexican limits established for myclobutanil or its metabolites in/on tomatoes or processed tomato products. Therefore, no compatibility problems exist.

Recommendations

We recommend against the proposed tolerances of 0.3 ppm for the r.a.c. tomatoes and various proposed tolerances ranging from 0.4 to 5.0 ppm for tomato processed commodities for the fungicide myclobutanil [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite RH-9090 [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] because of conclusions 1b, 3, 4, 5, 6, 7, 8, and 9.

Detailed Considerations

Manufacturing Process and Formulation

The synthesis and impurities of technical myclobutanil have been reviewed previously (See memo of 9/19/88, C. Trichilo). No residue problems are expected from the impurities at the reported levels. However, the petitioner must adequately define the myclobutanil technical grade active ingredient used in the formulations. Since myclobutanil has one asymmetric carbon,

then the petitioner must state if a racemic mixture , or an enriched enantiomer is used in the formulations. The petitioner should also state which enantiomer is fungicidally active.

Proposed Use

Rohm and Haas proposes to use Rally 40W fungicide to control powdery mildew (Leveillula sp.), rhizoctonia fruit rot, or septoria leaf spot on tomatoes. Rally 40W is to be sprayed by ground or air equipment at rates of 2.5 to 4.0 oz./acre (1 to 1.6 oz.a.i./acre) using a minimum of 20 gallons of water/A by ground and 10 gallons of water/A by air. Applications of the fungicide are not to exceed

10 oz. (0.25 lb a.i.) per acre per season. Applications will be made from approximate bloom up to the day of harvest for fresh tomatoes and to within 5 days of harvest for processing tomatoes. A restriction "Do not exceed 21 days between application intervals" is included on the label. This product is not for application through any type of irrigation systems. Rally 40W is a water soluble fungicide and is not to be applied in diesel oils or summer spray tube oils as in ULV or LV uses.

CBTS does not distinguish between "fresh market" and "processed" tomatoes based upon the knowledge that "fresh market" tomatoes can be processed if the conditions arise. Therefore the minimum PHI of 0 days will be used to assess the field residues data for this tolerance request.

Nature of the Residue

No additional plant or animal metabolism studies were submitted with this petition. Radiolabelled studies have been conducted using wheat plants (field and greenhouse), wheat and grape seedlings in aqueous solution of RH-3866, apple trees, grape vines, rats, lactating cows, and laying hens. (See memos of 8/12/85 and 6/16/87, R. Loranger, 2/8/88, M. Nelson, and 9/30/92, J Stokes).

Plants

Metabolism data cannot be translated from the previous fruit and wheat studies for this tolerance request. The residues are not adequately understood for the proposed use in tomatoes. For a permanent tolerance request, a tomato metabolism study should be submitted using myclobutanil containing the 14C-radiolabel in the phenyl and triazole rings and at an adeqauate application rate to identify metabolites.

Animals

A metabolism study was conducted on 4 groups of 2 lactating dairy cows in each group. Each cow received a 14C mixture of RH-3866/RH-9090/RH-9089 (32:58:10) at dose levels equivalent to 1.2, 2.8, 12, and 38 ppm (based on average consumption of 14.6 kg/day). The 14C labelling occurred uniformly on the phenyl ring of RH-3866, and at carbons 3 and 5 of the triazole ring in RH-9090 and RH-9089. The animals were dosed orally for 10 consecutive days. One additional cow served as a control. Milk and excreta samples were collected daily and frozen. The animals were sacrificed 24 hours after the last dose, and collected samples of tissues were frozen. The radioactivity was determined by combustion and LSC techniques.

6

Structures of Myclobutanil and Its Metabolites

Distribution of 14C Activity in Dairy Cattle*
(as a percentage of):

	TOTAL DOSE Treatment level (ppm)				RECOVERED ACTIVITY Treatment level (ppm)			
Sample	1.2	2.8	12	38	1.2	2.8	12	38
Urine	39	32	36	32	47	53	54	50
Feces	43	28	30	31	52	47	45	49
Milk	0.06	0.44	0.46	0.34	0.07	0.73	0.69	0.53
Tissues	0.31	0.20	0.27	0.30	0.38	0.33	0.40	0.48
Total %:	82	61	67	64		N/A		

* (See memo of 2/8/88, M. Nelson)

14C Residues[1] in Dairy Cattle
from 10-Day Metabolism Study

	Feeding Levels[2,3]			
Tissue	1.2 ppm	2.8 ppm	12 ppm	38 ppm
Milk	0.008	0.030	0.095	0.258
Liver	0.047	0.108	0.321	0.965
Kidney	<0.024	<0.02	0.060	0.182
Fat	<0.02	<0.02	<0.02	0.073
Muscle	<0.02	<0.02	<0.02	0.098

1 Maximum values, in ppm, calculated as RH-3866.
2 (See memo of 2/8/88, M. Nelson)
3 The minimum quantifiable limit is 0.02 ppm in tissues and 0.005 ppm in milk.

In a second metabolism study lactating dairy cows received 5 daily oral doses of 14C-phenyl or 14C-triazole labelled RH-3866 equivalent to about 10 ppm in the diet. Milk was collected twice daily and excreta once daily. The cows were sacrificed 24 hrs after the last doses were administered. Milk residues peaked on the second day. Throughout the dosing period the milk activity ranged from 0.024 to 0.043 ppm (as RH-3866) for the phenyl label and 0.017 to 0.034 ppm for the triazole label. Tissue residues which were higher for the phenyl than the triazole labelled parent compound (RH-3866).

Tissue	Phenyl label (ppm)	Triazole label (ppm)
muscle	0.011 - 0.014	<0.0085 ppm
fats	0.024 - 0.036	<0.011 - 0.012
liver	0.42	0.024
kidney	0.11	0.059

The metabolites in milk were identified as glycol RH-294, alcohol

RH-9090 and four other polar compounds which were not identified. However, three of the unidentified compounds co-chromatographed with urine metabolites. The urine metabolites were defined as conjugates of RH-9090 and RH-9089. Other metabolites identified in the urine included glycol RH-294, alcohol RH-9090, and the hydroxy lactone. Most of the residues found in milk and tissue did not consist of the parent compound (RH-3866) per se.

Therefore, until the additional requested tomato metabolism and the 28-day feeding study are submitted and reviewed, we will reserve our comments on the nature of the residues in livestock for the proposed use on tomatoes.

Also, since tomatoes and its processed commodities will not be considered poultry feedstuffs, no additional poultry metabolism data will be needed for the requested use on tomatoes.

Analytical Method

The methodology to determine residues of parent RH-3866 and total metabolite RH-9090 (free plus conjugated) in tomatoes and tomato processed commodities is a RH-3866 total residue method (TR 34S-88-10, formerly TR 310-84-27) with minor modifications. (MRID #420192-02).

The method involves soxhlet-acid extraction of tomatoes to release RH-9090 conjugates, followed by basification. Ketone RH-9089 is reduced to the alcohol RH-9090 with sodium borohydride, the reaction mixture is extracted with hexanes, and this hexane extract is partitioned into methylene chloride. Samples are then cleaned-up by affinity chromatography, methylene chloride partitioning, and adsorption chromatography. RH-3866 is quantitated on a glc packed column with N/P detection. Residues of RH-9090 are analyzed on a glc megabore capillary column with EC detection. The method sensitivity is 0.01 ppm for both RH-3866 and RH-9090.

Recoveries of RH-3866 and RH-9090 Residues from Fortified Whole Tomatoes

Fortification Level(ppm)	% Recovery RH-3866 (avg)	% Recovery RH-9090 (avg)
0.1	75, 84, 122, 82	--
0.2	61	--
0.25	--	146
0.3	84	--
0.5	85, 137	83, 111
1.0	85, 121	51, 84
2.0	110	59, 84
3.0	80	78

Recoveries of RH-3866 and RH-9090 Residues from Fortified Processed Tomato Commodities

	Fortification Level(ppm)	% Recovery RH-3866 (avg)	% Recovery RH-9090 (avg)
canned	0.4	87	56
canned	1.5	83	70
catsup	0.5	82	89
catsup	2.0	100	85
dry pomace	0.25	116	68
dry pomace	2.0	94	106
juice	1.0	111	122
wet pomace	0.5	66	111
wet pomace	2.0	58	95

Successful method validations have been conducted by the Agency on TR-34S-88-10 (See memo of 4/14/88, M. Nelson). Chromatograms for the analyses of untreated controls, fortifications, standards, and treated samples were provided for all the tomato commodities, both r.a.c. and processed. Method TR 34S-88-10 is adequate for residues of parent myclobutanil (RH-3866) and metabolite RH-9090 in/on tomatoes and tomato processed commodities. Previously validated methods for the determination of RH-3866 and metabolite RH-9090 have been submitted to PAM II for publication (See memo of 7/18/89, M. Nelson).

However, we will reserve our final comments on the adequacy of the proposed enforcement analytical methodology for myclobutanil residues until the requested additional tomato plant metabolism study has been submitted and reviewed. If additional metabolites must be regulated, then analytical methodology to include validation, recovery, and storage stability data for each metabolite must be submiited.

Storage Stability

Storage stability of RH-3866 and RH-9090 residues in apples and grapes were discussed previously (See memos of 2/8/88 and 4/26/88, M Nelson). Apples and grapes fortified with RH-3866 and stored up to 2 years yielded recoveries between 84 and 108%. Grapes and apples treated with RH-3866, harvested, analyzed, stored over 3 years, and re-analyzed for both RH-3866 and RH-9090 show no change in the levels or composition of the residues.

No storage stability data were submitted on tomatoes or tomato processed commodities with this request. The samples were harvested by normal practices, shipped frozen and stored frozen (-10 C) at the laboratory. The tomato samples were stored between 14 to 18 months before analysis. The storage stability data submitted previously are not adequate for the purposes of this tolerance request. A storage stability study must be submitted for permanent tolerances reflecting the same storage conditions as the tomato samples (both r.a.c. and processed commodities) submitted in this petition. Also, if additional metabolites must be regulated, then storage stability data for each metabolite must be submiited.

Residue Data (MRID#'s 420192-01, 420192-02, 423107-01)

Nine field trials were conducted using RH-3866 (Rally 60DF) on tomatoes in nine different US tomato growing locations. Four or five applications of myclobutanil were made at 0.063 lb a.i./acre The proposed label rate allows up to 4 applications at 0.063 lb. a.i./A, up to 2 applications at 0.1 lb a.i./A or a combination of the two rates which are not to exceed a total of 0.25 lb a.i./A/yr. PHI's are 0 day for a fresh market tomatoes and 5 days for processing tomatoes. One trial conducted in Florida (MRID# 423107-01, submitted 4/24/92 as a supplemental data) made four applications for a total application of 0.34 lb a.i./A/season. No field residues data were submitted using applications at the maximum recommended rate of 0.1 lb a.i./A and the minimum 0 day PHI. The tomatoes were harvested at 0 day following the last treatment, and were analyzed for total residues (RH-3866, RH-9090, and RH-9089 glycoside conjugates converted to RH-9090).

Summary of Field Trial Residue Data

Location	Lbs. a.i./A	PHI (days)	Max. Residues (ppm) Total	RH-3866	RH-9090
CA	0.24	0	0.048	0.048	ND[1]
		5	0.033	0.033	ND
CA	0.24	0	0.067	0.067	ND
		5	0.074	0.074	ND
CA	0.24	0	0.047	0.047	ND
		5	0.039	0.039	ND
		10	0.028	0.028	ND
FL[2]	0.34	0	0.25	0.22	0.032
IN	0.30	0	0.050	0.050	ND
		4	0.037	0.037	ND
MI	0.24	0	0.091	0.091	ND
		4	0.030	0.030	ND
NJ	0.30	0	0.033	0.033	ND
		5	0.027	0.027	ND
OH	0.30	0	0.056	0.056	ND
		5	0.052	0.052	ND
SC	0.24	0	0.083	0.083	ND
		5	0.043	0.043	ND

[1]ND= nondetectable residue (0.003 ppm)
[2]Pesticide was applied at a 1.4X rate of the proposed seasonal

maximum of 0.25 lb a.i./A

No field residue data were submitted using applications at the maximum individual application rate of 0.1 lb a.i./A. Additional residue data must reflect the petitioner's proposed use pattern at the maximum rate and the minimum PHI for all tomatoes to include a cherry or salad size variety. Supporting storage stability data should be included. If additional metabolites must be regulated, then field residue data will be needed for these metabolites.

Processing study

A processing study for harvested tomatoes which were treated with 4 applications of myclobutanil at rates of 0.063 lb a.i./A and 0.125 lb a.i./A (totals of 0.25 and 0.50 lb a.i./A, respectively). Samples were harvested 5 days post-treatment and processed commercially. The processed fractions were analyzed for residues of myclobutanil and its major plant metabolite RH-9090 by analytical method TR 34S-88-10.

Unwashed tomatoes were used in the processed studies.

	Treatment Level, lb a.i./A	RH-3866, ppm	RH-9090, ppm	Combined (ppm)
whole fruit	0.25	0.033	0.0	0.033
juice	0.25	0.018	0.0	0.018
catsup	0.25	0.075	0.0	0.075
puree	0.25	0.043	0.02	0.045
paste	0.25	0.079	0.03	0.081
paste juice	0.25	0.040	0.045	0.085
wet pomace	0.25	0.25	0.0	0.25
dry pomace	0.25	0.43	0.0	0.43
whole fruit	0.50	0.042	0.021	0.063
juice	0.50	0.037	0.023	0.060
catsup	0.50	0.0	0.027	0.027
puree	0.50	0.049	0.025	0.074
paste	0.50	0.17	0.076	0.146
paste juice	0.50	0.015	0.064	0.079
wet pomace	0.50	0.026	0.006	0.032
dry pomace	0.50	1.03	0.012	1.042

Control samples: [commodity (RH-3866 ppm, RH-9090 ppm], whole fruit (0.03, 0.018), juice (0.032, 0.023), catsup (0.067, 0.0), puree (0.006, 0.012), paste (0.062, 0.014), paste juice (0.004, 0.053), wet pomace (0.0, 0.0), dry pomace (0.007, 0.0).

Some control samples had residues similar, or even slightly higher, than the treated samples. The petitioner should state if all samples were corrected for controls. Recoveries for spiked

residues are discussed in the analytical methodology section of this memo.

Concentration Factors:

	Treatment 0.25 lb a.i./A	0.50 lb a.i./A	Average
~~juice~~	0.55	0.95	0.75
~~catsup~~	2.27	0.42	1.34
puree	1.90	1.17	1.54
paste	3.30	3.90	3.60
~~paste juice~~	2.57	1.25	1.91
wet pomace	7.57	0.51[1]	7.57
dry pomace	13.0	16.5	14.8

X HAFT

[1] This value was not used to calculate the average concentration for wet pomace because it appears to be an error. Myclobutanil and its metabolite RH-9090 are expected to occur primarily as surface residues for this proposed use, and this assumption is supported by the other residue values for wet and dry pomace. Wet and dry pomace would contain a high percentage of the tomato skin.

The submitted processing study shows concentrations of myclobutanil residues in catsup, puree, paste, paste juice, and pomace when the myclobutanil formulation was applied at a rate of 0.25 lb a.i./A/yr. As expected, there appears to be no concentration in juice. We will consider the catsup, puree, and paste juice together as tomato processed products (excluding paste) and have calculated average concentration values of 1.6X for the residues of parent RH-3866 and its metabolite RH-9090 on these products. Therefore, food additive tolerances are needed for tomato processed products (excluding paste) at 0.6 ppm, for paste at 1.2 ppm, and for pomace (wet and dried) at 5 ppm. The petitioner should also determine the quantitation limits for myclobutanil and metabolite RH-9090 (and any other regulated metabolites if so needed) in whole tomatoes and tomato processed commodities.

However, we will reserve our final comments on the adequacy of the processing study for myclobutanil residues until the requested additional tomato plant metabolism study has been submitted and reviewed. If additional metabolites must be regulated, then processing data will be needed for these metabolites.

Meat, Milk, Poultry, and Eggs

Tomatoes and processed tomato waste are animal feed items for beef/dairy cattle only; therefore, secondary residues are a concern in meat and milk. Tolerances have been established in meat and milk. Feeding studies were not submitted with this request, but metabolism studies were previously used to determine secondary

residues in meat, milk, and eggs (See memos of 2/8/88, M. Nelson, 6/16/87, R. Loranger and, 9/30/92, J. Stokes).

However, for a permanent tolerance on tomatoes, the petitioner must submit a conventional 28-day feeding study for lactating dairy cattle at 1X, 3X, and 10X levels based upon the maximum regulated residues expected in all potential feedstuffs. The established tolerances in meat and milk will be reevaluated after the additional feeding study is submitted to support a permanent tolerance on tomatoes.

Other Considerations

There are no Codex, Canadian, or Mexican limits established for myclobutanil or its metabolites in/on tomatoes or processed tomato products. Therefore, no compatibility problems exist.

cc: J. Stokes (CBTS); PP#2G4059; R.F.; Circulation
RDI: RLoranger:10/21/92
H7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:10/22/92

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 13 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#1F4030/H5616. Response to RD Request. Additional Comments on the Need for A Metabolism Study of Myclobutanil on Tomatoes. No MRID#'s, CBTS# 12163, and Barcode#192891.

FROM: Jerry B. Stokes, Chemist
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

THRU: Philip V. Errico, Section Head
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

TO: Clarence Lewis/Julie Fairfax, PM-21
Fungicide-Herbicide Branch
Registration Division (H7505C)

Rohm and Haas Company by telefax inquiry (See Attachment 1, (Richard Costlow to Clarence Lewis), has requested a meeting to discuss that CBTS reconsider our need we expressed for a tomato metabolism study for fungicide myclobutanil.

CBTS has previously stated:

"Metabolism data cannot be translated from the previous fruit and wheat studies for this tolerance request. The residues are not adequately understood for the proposed use in tomatoes. Therefore, a tomato metabolism study should be submitted using myclobutanil containing the 14C-radiolabel in the phenyl and triazole rings and at an adequate application rate to identify metabolites." (See memo of 10/26/92, J. Stokes).

Comments/Conclusions:

Radiolabeled studies have been conducted using wheat plants (field and greenhouse), wheat and grape seedlings in aqueous solution of

RH-3866, apple trees, and grape vines. (See memos of 8/12/85 and 6/16/87, R. Loranger, 2/8/88, M. Nelson, and 9/30/92, J Stokes). In the wheat metabolism data, triazole conjugates were found which were not present in the apple or grape studies. In addition, although apple and grape are in different crop groups, these are both perennial crops. Our guidelines require metabolism studies from three dissimilar crops, and that a similar metabolic route exist in all three. Thus, an additional study with an annual, rapidly growing crop such as tomato, would yield a better data base from which to make decisions on the residues of concern for myclobutanil in tomatoes, and possibly other raw agricultural commodities.

Based upon the above comments, CBTS still requests that the petitioner provide the tomato metabolism study. Therefore, CBTS does not believe a meeting is necessary at this time.

cc: J. Stokes (CBTS); PP#2F4030; R.F.; Circu
RDI: PErrico:7/12/93:RLoranger:7/12/93
H7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:7/12/93

INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19106, U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-6335 TELECOPIER (215) 592-3377

ATTACHMENT 1

ROHM HAAS COMPANY

18 June, 1993

Mr. Jerry B. Stokes VIA TELEFAX
US EPA OPP HED (H7509C)
Document Processing Desk (Correspondence)
Room 266A, Crystal Mall Two
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Stokes:

SUBJECT: MYCLOBUTANIL - 707-212, 707-215 and 707-221;
Request for a Meeting on Tomato Registration (PP 1F4030)

The Registration Division requested that I put our request to you in writing.

In your review of this application you indicated that a tomato metabolism study would be required for a permanent registration. Based on our reading of your review we assume this is because your concluded that the wheat metabolism data indicated triazole conjugates as metabolites not present in apples and grapes. We would like to present to you the reasons this occurs and after we have explained the origin of the metabolites, discuss with you the relevance this has to tomatoes. We believe that the metabolism in plants is consistent across species and would like the opportunity to present our case. I anticipate that Rohm and Haas would be represented by Dr. Stanley Stavinski, Mr. Walter Zogorski, and me.

If you have questions about our review please call at your convenience, but please call to establish a meeting time at EPA. My phone number is (215) 592-3581.

Best Regards,

Richard D. Costlow, Ph.D., D.A.B.T.
Product Registration Manager
Agricultural Chemicals Registration and
Regulatory Affairs Department

CC:
Mr. Clarence Lewis (PM21) VIA FAX
Registration Division

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 13 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#1F4030/H5616. Amendment dated May 12, 1994. Myclobutanil in/on Tomatoes and Tomato Processed Fractions. MRID #'s 432304-00 and 432304-01. CBTS# 13799. DP Barcode D203587.

FROM: Jerry B. Stokes, Chemist
Chemistry Branch/Tolerance Support
Health Effects Division (7509C)

THRU: Philip V. Errico, Section Head
Chemistry Branch/Tolerance Support
Health Effects Division (7509C)

TO: Steven Robbins, Acting PM-21
Fungicide-Herbicide Branch
Registration Division (7505C)

Rohm and Haas Company has submitted a cover letter dated May 12, 1994, and a response to CBTS request for a tomato metabolism study for PP#1F4030. The registrant has requested the use of the fungicide myclobutanil [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, RH-3866] in/on tomatoes.

Comments/Conclusions

Metabolism data can be translated from the previous fruit and wheat studies for this tolerance request. The residues are now adequately understood for the proposed use in tomatoes. Therefore, **a tomato metabolism study will no longer be required** for the proposed use in/on tomatoes.

Recommendations

We recommend against the proposed tolerances of 0.3 ppm for the r.a.c. tomatoes and various proposed tolerances ranging from 0.4 to 5.0 ppm for tomato processed commodities for the fungicide myclobutanil [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-

propanenitrile] and its metabolite RH-9090 [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] because of outstanding deficiencies 1b, 2, 4, 6, 7, 8, and 9 (See memo of 10/26/92, J Stokes).

Detailed Considerations

Nature of the Residue

No additional plant or animal metabolism studies were submitted with this request. Radiolabelled studies have been submitted previously using wheat plants (field and greenhouse), wheat and grape seedlings in aqueous solution of RH-3866, apple trees, and grape vines.

CBTS previously commented: "Metabolism data cannot be translated from the previous fruit and wheat studies for this tolerance request. The residues are not adequately understood for the proposed use in tomatoes. For a permanent tolerance request, a tomato metabolism study should be submitted using myclobutanil containing the 14C-radiolabel in the phenyl and triazole rings and at an adeqauate application rate to identify metabolites." (See memo of 10/26/92, J. Stokes).

CBTS further commented: "Radiolabeled studies have been conducted using wheat plants (field and greenhouse), wheat and grape seedlings in aqueous solution of RH-3866, apple trees, and grape vines. (See memos of 8/12/85 and 6/16/87, R. Loranger, 2/8/88, M. Nelson, and 9/30/92, J Stokes). In the wheat metabolism data, triazole conjugates were found which were not present in the apple or grape studies. In addition, although apple and grape are in different crop groups, these are both perennial crops. Our guidelines require metabolism studies from three dissimilar crops, and that a similar metabolic route exist in all three. Thus, an additional study with an annual, rapidly growing crop such as tomato, would yield a better data base from which to make decisions on the residues of concern for myclobutanil in tomatoes, and possibly other raw agricultural commodities." (See memo of 07/13/92, J. Stokes).

Registrant's Response dated May 12, 1994:

"Triazole alanine and triazole acetic acid are compounds of low toxicity which occur naturally in plants. EPA has not required these compounds to be included in tolerance expressions for the triazole fungicides. They are not considered part of the toxicologically relevant residue. We believe the total toxicologically relevant residue is consistent across all the crop metabolism studies and that an additional tomato metabolism study should not be required.

Table 1 summarizes the metabolite profile for grapes, apples, and

wheat (MRID 073599). The only whole molecule residues present are RH-3866. Parent, RH-9089, and RH-9090 conjugates. Please note that this metabolic profile is consistent in all crops. In addition, Triazole Alanine (TA) and Triazole Acetic Acid (TAA) are present in wheat. Structures are illustrated in Figure 1. The TA and TAA residues arise from decomposition of myclobutanil in soil to free triazole.

Free triazole is a soil metabolite of many triazole containing fungicides, including myclobutanil. Translocation of the triazole or its conjugates (TA and TAA) occurs into plants. There is also ample evidence that triazole itself, as well as it conjugates, are naturally occurring materials which are ubiquitous in nature. Evidence for the natural occurrence of triazole compounds has been previously submitted to EPA by Rohm and Haas Company and others in support of a number of triazole containing compounds. Included in the evidence are the detection of free triazole in untreated soil samples, the characterization of a triazole conjugate from cultured soil microorganisms, and the finding of conjugates (TA/TAA) at relatively high levels in untreated crops. The preexistence of triazole compounds in the environment at significant levels coupled with the low toxicity profile previously reviewed by the EPA for these materials supports the exclusion of the triazole conjugates from the tolerance expression for myclobutanil. Precedent for the exclusion of triazole conjugate residues from the tolerance expression can be found in the EPA decisions on propiconazole, a triazole fungicide, which also releases triazole in soil.

Rohm and Haas Company is a member of the Triazole Alanine Group (#056736-Q) which shares a common database for these triazole related issues with EPA. Other group members are Bayer, ICI, and Ciba-Geigy. TA and TAA are common metabolites for all triazole fungicides. For previous registration of all triazole fungicides the EPA has determined that TA and TAA are not toxicologically relevant and should not be included in the tolerance expression. Relevant EPA comments are below:

Conclusions: '1. Plants contain natural components which contain the triazole moiety. 2. Background residues of the triazole-containing components appear at high levels, and such levels can mask the contribution of triazoles due to treatment with propiconazole (TILT). 3. The present data submissions resolve questions on the presence of triazole-containing components in crop backgrounds.' (EPA Review CBTS, A. Smith and C. Trichilo, Dec. 31,1986).

'Based primarily on the database indicating relatively low toxicity of triazole alanine and RCB's advisory that triazole compounds occur naturally in plants (e.g. peanuts, pecans, cereal grains) at high levels relative to any contribution attributable to the application of (triazole fungicide) TOX Branch has determined that at this time there is no compelling toxicological basis for

requiring additional metabolism studies or analytical methodologies specific for the triazole moieties contributed by (triazole fungicide).' (EPA Review Tox, A. Katz, M. Von Gemert, T. Farber, May 8,1987).

Thus, it is reasonable to exclude TA and TAA consideration in the metabolic profile and the tolerance expression without TA and TAA, myclobutanil exhibits a consistent metabolic profile in all crop metabolism studies.

Therefore, Rohm and Haas believes this satisfied all EPA guidelines. The guidelines require metabolism studies for three dissimilar crops, and that a similar metabolic route exist in all three. For the total residue of concern in the tolerance expression, the myclobutanil metabolic route is the same in three dissimilar crops, vines (grapes), pomefruit (apples - trees), and a fast growing annual (wheat). We believe a tomato metabolism study is not required. Rohm and Haas has already received reviews of our petition for a tolerance on cucurbits which concludes that the plant metabolism is adequately understood (2F4155)." (Comments extracted from MRID#432304-01).

CBTS Comments/conclusions:

CBTS agrees with the registrant. **Deficiency #3 (See memo of 10/26/92, J. Stokes) is now resolved.** A metabolism study for tomatoes will not be needed. Therefore, comments made in this same memo in regard to possible additional data needs for additional metabolites for analytical methodology (deficiency #5, same memo), storage stability (deficiency #6, same memo), residue data for the raw agricultural and processed commodites (deficiencies #"7 and 8, same memo), and the 28-day feeding study (deficiency #9, same memo) are no longer relevant.

Therefore, the methodology to determine residues of parent RH-3866 and total metabolite RH-9090 (free plus conjugated) in tomatoes and tomato processed commodities is a RH-3866 total residue method (TR 34S-88-10, formerly TR 310-84-27) with minor modifications, and is adequate as an enforcement method for the proposed use. **Deficiency #5 (memo of 10/26/92, J. Stokes) is now resolved.**

Although storage stability will not be needed for additional metabolities, storage stability data for tomatoes and tomato processed commodities are still needed for parnet and its metabolite RH-9090. **Deficiency #6 (memo of 10/26/92, J. Stokes) is still outstanding.**

Likewise, residue data will not be needed for additional metabolities, but additional residue data are still needed. **Deficiencies #7 and #8 (memo of 10/26/92, J. Stokes) are still outstanding.**

Previously, for a permanent tolerance on tomatoes, the petitioner was requested to submit a conventional 28-day feeding study for lactating dairy cattle at 1X, 3X, and 10X levels based upon the maximum regulated residues expected in all potential feedstuffs. This feeding study should be conducted using the parent, and all samples should be analyzed for the parent myclobutanil [α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, RH-3866] and both the free and bound forms of its metabolite [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, RH-9090]. **Deficiency #9 (memo of 10/26/92, J. Stokes) is still outstanding.** (See memo of 10/26/92, J. Stokes for details of deficiencies).

Deficiencies #1b, #2, and #4 (memo of 10/26/92, J. Stokes) are also still outstanding.

cc: J. Stokes (CBTS); PP#1F4030; R.F.; Circulation
RDI: PErrico:07/11/94:RLoranger:07/11/94:EHaeberer:07/13/94
7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:07/13/94

RECORD OF COMMUNICATION

☒ PHONE CALL ☐ DISCUSSION ☐ FIELD TRIP ☐ CONFERENCE
☐ OTHER (SPECIFY)

(Record of item checked above)

TO: CBTS Files

FROM: Jerry B. Stokes

DATE: 1/5/93

TIME:

SUBJECT: Data requirements for myclobutanil treated cherry tomatoes

SUMMARY OF COMMUNICATION

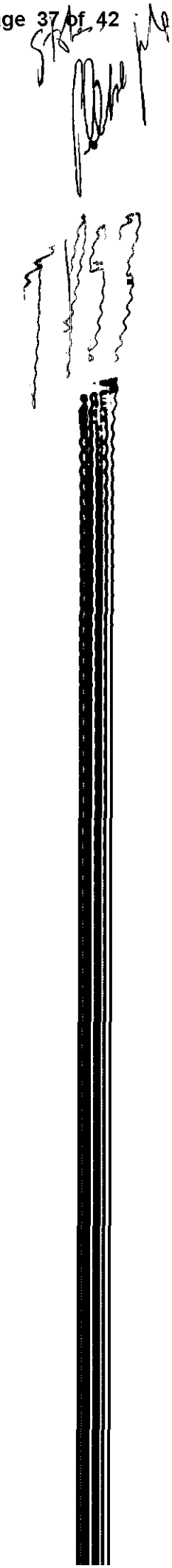
Phil and I advised Ed Carley (215-592-6731) on 12/14/92 that the only outstanding requirement for the myclobutanil EUP for tomatoes was a Revised Section F. The registrant will supply the Section F.

In additional, we told him that for a Section 3 registration of myclobutanil on tomatoes CBTS also needs field residue data for other tomatoes besides the cherry variety because no data were submitted that reflected the maximum label rate of 0.1 lb a.i./A. He stated that he thought a second study from FL had been submitted. He will check the status of this study. We also suggested that another option in lieu of the collection of field trial data at the 0.1 lb a.i./A, the registrant could consider a label change to decrease the application rate to 2.5 oz/A (0.063 lb. a.i./A). He will revise the label rate. We stated that we will still need to review the second study for FL. If this data reflect similar results as the previous studies, and the maximum allowable label rate is decreased to 2.5 oz/A, CBTS will not require additional data for normal size tomatoes. But, we will still need the data for cherry tomatoes even with a label change. CBTS could also still agree to recommending a tomato tolerance (except cherry size) with an expiration date. CBTS would then review the proposed data for the cherry size tomato and would reevaluate the tomato tolerance and would recommend any change that might be needed based on this data at that time.

CONCLUSIONS, ACTION TAKEN OR REQUIRED

None

INFORMATION COPIES TO: PP#2F4030; R.F.; Circu.; J. Stokes



STB, Please FU

TPS3

ENVIRONMENTAL PROTECTION AGENCY

[PF-560; FRL-4050-3]

Pesticide Tolerance Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions (PP) and food and feed additive petitions (FAP) proposing the establishment of regulations for residues of certain pesticide chemicals in or on certain agricultural commodities. This document also corrects a previous filing.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for

P2

inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, contact the product manager (PM) named in each petition at the following office location/telephone number:

Product Manager	Office location/ telephone number	Address
George LaRocca (PM-13).	Rm. 202, CM #2, 703-305-6100.	1921 Jefferson Davis Hwy., Arlington, VA
Phil Hutton (PM-18).	Rm. 213, CM #2, 703-305-7690.	Do.
Dennis Edwards (PM-19).	Rm. 207, CM #2, 703-305-6386.	Do.
Susan Lewis (PM-21).	Rm. 227, CM #2, 703-557-1900.	Do.
Joanne Miller (PM-23).	Rm. 237, CM #2, 703-305-7830.	Do.
Robert Taylor (PM-25).	Rm. 241, CM #2, 703-557-1600.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions and food/feed additive petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

Initial Filings

1. *PP 1F4008.* BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR 180.380 by establishing a regulation to permit combined residues of the fungicide vinclozolin, 3-(3,5-dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione and its metabolites containing the 3,5-dichloro-aniline moiety, in or on potatoes at 0.1 ppm. (PM-21)

2. *FAP 2H5623.* BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 185 by establishing a food additive regulation to permit combined residues of vinclozolin, 3-(3,5-dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione, and its metabolites containing the 3,5-dichloro-aniline moiety in or on dry potato peel at 3.0 ppm and potato granules, flakes, and chips at 0.2 ppm. (PM-21)

3. *PP 1F4011.* ICI Americas, Inc., Agricultural Products, Wilmington, DE 19897, proposes to amend 40 CFR part 180 by establishing a regulation to permit combined residues of the herbicide acetochlor, 2-chlor-N-(ethoxymentyl)-N-(ethyl-6-methylphenyl)-acetamide, in or on corn grain at 0.05 ppm, corn forage at 1.0 ppm, and corn fodder at 1.5 ppm. (PM-23)

4. *PP 1F4013.* American Cyanamid Co., Agricultural Research Division, P.O. Box 400, Princeton, NJ 08543-0400, proposes to amend 40 CFR 180.447 by establishing a regulation to permit combined residues of imazethapyr, (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-yl]-5-ethyl-3-pyridine-carboxylic acid) as its ammonium salt, and its metabolite 2-[4,5-di-hydro-4-methyl-4-(1-methylethyl-5-oxo-1H-imidazol-2-yl-5-(1-hydroxyethyl)-3-pyridine carboxylic acid both free and conjugated in or on alfalfa forage and hay at 3.0 ppm. Analytical method used is gas chromatography. (PM-25)

5. *PP 1F4016.* Ciba-Geigy Corp., Agricultural Division, P. O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.414 by estab- lishing a regulation to permit combined residues of insecticide cyromazine, N-cyclo-propyl-1,3,5-triazine-2,4,6-triamine, plus its major metabolite melamine, 1,3,5-triazine-2,4,6-triamine, calculated as cyromazine in or on the leafy vegetables crop group at 10 ppm. (PM-18)

6. *PP 1F4029.* E. I. Du Pont Co., Walker's Mill, Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, proposes to amend 40 CFR 180.428 by establishing a regulation to permit combined residues of the herbicide metsulfuron methyl, 2-[[[[(4- methoxy-6-methyl-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]benzoate], and its metabolite methyl 2-[[[[(4methoxy-6-methyl-1-3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate in or on wheat grain at 0.1 ppm, wheat straw at 0.3 ppm, barley grain at 0.1 ppm, and barley straw at 0.3 ppm. (PM-25)

7. *PP 1F4030.* Rohm & Haas Co., Regulatory Affairs Department, Independence Mall West, Philadelphia, PA 19105, proposes to amend 40 CFR 180.443, by establishing a regulation to permit combined residues of the fungicide myclobutanil, alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, and its metabolite alpha-(3-hydroxybutyl)-alpha-4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) in or on tomatoes at 0.3 ppm. (PM-21)

8. *PP 1H5616.* Rohm & Haas Co., Regulatory Affairs Department, Independence Mall West, Philadelphia, PA 19105, proposes to amend 40 CFR 180.443 by establishing a regulation to permit combined residues of the fungicide myclobutanil, alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile, and its metabolite alpha-(3-hydroxybutyl)-alpha-4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) in or on tomato (puree) at 0.4 ppm, tomato (catsup) at 0.7 ppm, tomato (paste juice) at 0.8 ppm, tomato (paste) at 2.0 ppm, tomato (wet pomace) and tomato (juice) at 3.0 ppm, and tomato (dry pomace) at 5.0 ppm. (PM-21)

9. *PP 2F4036.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the herbicide N-(2-6-difluorophenyl)-5-methyl-(1,2,4)-triazolo[1,5a]-pyrimidine-2-sulfonamide, coded DE-498, in or on corn, fodder at 0.05 ppm; corn, forage, at 0.05 ppm; corn, grain at 0.05 ppm; and soybeans at 0.05 ppm. (PM-23)

10. *PP 2F4039.* Sentry, Inc., P. O. Box 426, Buckeye, AZ 85326-0090, proposes to amend 40 CFR part 180 by establishing a regulation to exempt from the requirement of a tolerance the tomato pinworm insect pheromone NoMate TPW Spiral [[E/Z]-4-tridecen-1-yl acetates]. (PM-18)

11. *PP 2F4040.* Espro, Inc., 1015 15th St., NW., Washington, DC 20005, proposes to amend 40 CFR part 180 by establishing a regulation to exempt from the requirement of a tolerance SPOD-X (spodoptera exiqua) for use against the beet armyworm. (PM-18)

12. *PP 2F4041.* BASF Corp., Agricultural Products Group, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR 180.412 by establishing a regulation to permit combined residues of Poast herbicide, 2-[1-(ethoxyimino)butyl]-5-[2-ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one moiety (calculated as the herbicide), in or on canola/rape seed at 35.0 ppm and canola/rape forage at 3.5 ppm. Analytical method used is gas chromatography. (PM-25)

13. *PP 2F4046.* AgriDyne Technologies, Inc., 417 Wakara Way, Salt Lake City, UT 84108, proposes to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for azadiracthin as an insect growth regulator and/or antifeedant applied to

seeds, cuttings, transplants, and plants. (PM-18)

14. *PP 2F4053*. Ciba-Geigy Corp., Agricultural Division, P. O. Box 18300, Greensboro, NC 27419, proposes to amend 40 CFR 180.414 by establishing a regulation to permit combined residues of the insecticide cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine), and its principal metabolite, melamine (1,3,5-triazine-2-4,6-triamine), calculated as cyromazine in or on cucurbit vegetables at 2.0 ppm. (PM-18)

15. *PP 2F4055*. Hoechst-Roussel Agri-Vet Co., Route 202-206, P.O. Box 2500, Somerville, NJ 08876-1258, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the insecticide deltamethrin (1R,3R)-3(2,2-dibromovinyl)dimethylcyclopropane-carboxylic acid (S)-alpha- cyano-3-phenoxybenzyl ester and its metabolites, trans-deltamethrin: (1R,3S)-3(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylic acid (S)-alpha-cyano-3-phenoxybenzyl ester and alpha-R-deltamethrin: (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylic acid (R)-alpha-cyano-3-phenoxybenzyl ester calculated as parent, in or on cottonseed at 0.02 ppm. (PM-15)

16. *PP 2F4058*. Regulatory Assistance Corp., 17 Clearview Circle, Hopewell Junction, NY 12533, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of herbicide UMP-488, 1-methoxy-1-methyl-3-[4-(3,4-dihydro-2-methoxy-2,4,4-trimethyl-7-benzopyranyloxy) phenyl] urea, in or on field corn grain, forage, fodder, and silage at 0.01 ppm. (PM-23)

17. *PP 2F4061*. Du Pont, Agricultural Products, Walker's Mill, Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, proposes to amend 40 CFR 180.294 by establishing a regulation to permit residues of benomyl, methyl 1-(butylcarbamoyl-2-benzimidazolecarbamate, in or on rice straw at 20.0 ppm. (PM-21)

18. *PP 2F4063*. Ciba-Geigy Co., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.408, by establishing a regulation to permit combined residues of the fungicide metalaxyl, N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester, and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester, each expressed as metalaxyl equivalents, in or on grass forage at 10.0 ppm and grass hay at 20.0 ppm. (PM-21)

19. *PP 2F4067*. E.I. du Pont de Nemours & Co., Inc., Agricultural Products, Walker's Mill, Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, proposes to amend 40 CFR 180.253 by establishing a regulation to permit residues of the insecticide methomyl, (S-methyl N-[methylcarbamoyl)oxy] thioacetimidate, in or on dried pea seed at 0.2 ppm, pea hay at 10.0 ppm, bean hay at 10.0 ppm, lentil forage at 10.0 ppm, lentil hay at 10.0 ppm, and soybean hay at 10.0 ppm. (PM-19)

20. *FAP 2H5624*. NOR-AM Chemical Co., 3509 Silverside Rd., P.O. Box 7495, Wilmington, DE 19803, proposes to amend 40 CFR 186.278, by establishing a food additive regulation to permit residues of the herbicide phenmedipham, 3-methoxycarbonylaminophenyl-3'-methylcarbanilate in or on sugar beet pulp, dehydrated at 0.5 ppm and sugar beet molasses at 0.2 ppm. (PM-25)

Corrected Filing

In the **Federal Register** of December 13, 1991 (56 FR 65081), EPA issued incorrectly an initial filing of PP 1F4004. It is corrected to read as follows:

PP 1F4004. Valent U.S.A. Corp., 1333 North Carolina Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA 94596-8025, proposes residues of (E)-(R)-1-(2,4-dichlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pent-1-en-3-ol and its related isomers in or on peanuts and peanut hulls and for residues of (R)-1-(2,4-dichlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pent-1-en-3-ol, its related isomers and its metabolite, (E)-(R)-1-(2,4-dichlorophenyl)-4-methyl-4-hydroxymethyl-2-(1H-1,2,4-triazol-1-yl)-pent-1-en-3-ol in meat, milk, eggs, and the appropriate byproducts resulting from application of SPOTLESS 25W according to the proposed label of SPOTLESS 25W at rates ranging from 5 to 16 oz/acre (total individual treatment rates up to 8 oz/acre and a phi of 28 days for the higher rates). The grazing of peanut hay and vines is restricted by the proposed label. Peanut nutmeats at 0.1 ppm, peanut hulls at 3.0 ppm, eggs at 0.01 ppm, milk at 0.01 ppm, meat and fat of cattle, goats, hogs, horses, poultry, and sheep at 0.01 ppm, meat byproducts (except liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm, meat byproducts of poultry at 0.01 ppm, liver of cattle, goats, hogs, and horses and sheep at 0.50 ppm. Tolerances are also proposed for residues of (E)-(R)-1-(2,4-dichlorophenyl)-2,4-dimethyl-2-(1H-1,2,4,-triazol-1-yl)pent-1-en-3-ol and its related isomers in or on commodities of rotational crops planted no sooner than at specified intervals in the proposed label after a final application of SPOTLESS 25W to peanut plants. Wheat forage and straw at 0.2 ppm, corn silage and forage at 0.05 ppm, corn fodder at 0.1 ppm, sorghum, silage, fodder, hay and forage at 0.05 ppm, soybean hay and forage at 0.05 ppm, peanuts, vines, and hay at 0.05 ppm. (PM-21)

Authority: 7 U.S.C. 136a.

Dated: February 21, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 92-5063; Filed 3-10-92; 8:45 am]

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END OF DOCUMENT